DETAILED ACTION

Claim Rejections - 35 USC § 102

Claims 1, 2, 4-22, 25-36, 38-40, 42-44, 46-48 and 50-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Swanson et al. US 2007/0048378 A1.

This rejection has been withdrawn in view of Applicant's claim of the priority application 09/164,351. See Request for Corrected Filing Receipt filed 12/30/11.

Claim Rejections - 35 USC § 103

Claims 1, 2, 4-22, 25-36, 38-40, 42-44, 46-48 and 50-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al. US 2007/0048378 A1, in view of Baichwal US 6,093,420.

This rejection has been withdrawn in view of Applicant's claim of the priority application 09/164,351. See Request for Corrected Filing Receipt filed 12/30/11.

Claims 1, 2, 4-9, 11-22, 25-36, 38-40, 42-44, 46-48 and 50-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liversidge et al. US 5,552,160, Baichwal US 6,093,420.

Liversidge teaches a dispersible particle composition comprising nanoparticulate drug and a surface modifier adsorbed on the surface of the drug. See abstract; columns 3-4; and claims. Suitable surface modifiers are found in columns 3-4. Drugs include naproxen, indomethacin, and ibuprofen (claim 5). Drug in crystalline phase is

found in column 2, lines 45-50. Liversidge further teaches the particle has an average particle diameter of less than 400 nm (claim 2).

Liversidge does not expressly teach formulating the nanoparticulate composition into a controlled release dosage form.

Baichwal teaches a sustained release dosage form comprising NSAID dispersed uniformly in a sustained release carrier (column 5, lines 65 through column 6, lines 1-30; column 9; and claims 19-22).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the nanoparticulate composition of Liversidge in a matrix tablet dosage form taught by Baichwal. This is because Baichwal teaches a polymer matrix useful for the controlled release of an NSAID, because Baichwal teaches that uniformly dispersing an NSAID in a polymer matrix is well known in the art, and because Liversidge teaches that the resulting nanoparticles can be prepared with pharmaceutically well-known carriers in the art (column 6, lines 62-67).

Response to Arguments

Applicant's arguments filed 12/30/11 have been fully considered but they are not persuasive.

Applicant argues that there is no reason that one of ordinary skill in the art would have combined the teachings of the references. It is unclear, however, why the skilled artisan would have any reason to combine the teachings of the cited art. "It can be important to identify a reason that would have prompted a person of ordinary skill in the

relevant field to combine the elements in the way the claimed new invention does." KSR International Co. v. Teleflex Inc., 550 U.S. 398,418 (2007).

However, in response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, Liversidge teaches coating the drug particle with the claimed surface stabilizer and the claimed rate controlling polymer. It is noted that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). However, to be more significant, Baichwal teaches the use of the same rate controlling polymers to obtain a sustained/controlled release composition. See for example the teaching in column 7, lines 65 through column 8, lines 1-8.

Applicant argues that the combined teachings of Liversidge and Baichwal fail to render the claimed invention obvious. This is because Liversidge is silent as to a

controlled release formulation, and Baichwal fails to meet at least the recited high molecular weight rate controlling polymers. More specifically, Baichwal's composition has a "unique dissolution profile, e.g., the initial release of ibuprofen [the active agent] at only 2 hours after in-vitro and the much slower prolonged release of the remaining ibuprofen is caused by the 'swelling' and 'gelling' properties of the xanthan gum and the cross-linking agent upon exposure to an environment fluid." See column 5, line 65, through column 6, line 3, of Baichwal.

However, in response to Applicant's argument with respect to the unique dissolution profile taught by Baichwal, the Examiner notes that the rejected claims do not recite any particular release profile, let alone preclude the unique release profile taught by Baichwal. As such, the 103(a) rejection over Liversidge and Baichwal is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. TRAN whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/S. TRAN/
Primary Examiner, Art Unit 1615